510(K) SUMMARY

D-SPECT SYSTEM

OCT 2 0 2006

510(k) Number K 062450

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Date Prepared: August 2006

Trade Name: D-Spect™ Cardiac Scanner System

Classification Name: CFR Classification section 892.1200 (Product code KPS)

Classification: Class II medical Device

Predicate Device: The D-Spect™ Cardiac Scanner System is substantially equivalent to a combination of the following predicate devices:

- Virgo (K031825) manufactured by 3D, Danish Diagnostic Development A/S (device a.k.a C.Cam, owned by Siemens Medical). Virgo is a Gamma Camera system (SPECT) which is intended to detect the location and distribution of gamma ray radionuclides similar to the D-Spect™ device.
- Cardiarc (K053062) manufactured by Cardiarc Ltd. Cardiarc is a SPECT imaging device which is intended for production of SPECT clinical images of the heart in nuclear medicine applications similar to the D-Spect™ device.
- Predicate devices for device accessory used for identifying patient:
- **a)** SmartBand (Class I 510(k) exempt), provides patient identification
- **b)** CareCheck (BK040053)- used in blood banks; provides patient and product identification.
- **c)** VeriChip implantable RFID Transponder (K033440).

Device Description: Spectrum Dynamics' D-Spect™ Cardiac Scanner System is a SPECT device, which is designed to perform myocardial perfusion imaging. The device is comprised of a detector head, gantry, and patient chair. Device operation is controlled from an acquisition station console. The system is supported by use of data-transfer accessories (RFID tags), which are attached to the patient's wrist and to the syringe containing the radio-pharmaceutical agent, for patient and syringe positive identification. The cardiac gamma camera is designed such that there are no external moving parts that surround the patient. Detector boards rotate within the closed

detector head. The special scanning geometry and detector technology, enable shorter scan times.

Intended Use / Indication for Use: D-SPECT is an emission computed tomography system intended to detect the location and distribution of gamma ray radionuclides in the body and produce cross-sectional images through computer reconstruction of the data. The device includes display equipment, patient and equipment supports, component parts, and accessories. D-SPECT is primarily intended for cardiac applications. D-SPECT supports radionuclides within the energy range of 40 -170 keV.

Comparison of Technological Characteristics with the predicate device:

D-Spect as other SPECT devices uses arrays of collimators, crystals, and position detection circuits to obtain clinical information from patients injected with gamma emitting radionuclide materials. The operating principle is the same basic principle and the same basic technology is used in all SPECT devices, including the Virgo and Cardiarc predicate devices. Although the design of detector boards (10 boards rotating on their vertical axis) is different compared to conventional SPECT cameras (with two crystals moving around the patient), the principle of photon detection is identical and the resulting images are identical to those of other devices. All of the above features are similar to these features in the predicate devices.

Performance Standards: None.

The design of the D-Spect™ Cardiac Scanner System conforms to the following voluntary standards:

IEC/EN-60601-1: Medical Electrical Equipment; Part 1: General Requirements for Safety. Second edition (1990), including amendments #1(1993), #2(1995), #13(1996).
IEC/EN 60601-1-2: Medical Electrical Equipment; Part 1-2: Collateral Standard: Electromagnetic Compatibility- Requirements and Tests (2001)
NEMA NU 1: Performance Measurements of Scintillation Cameras (1994) (relevant sections).

Non-Clinical Test Data: The D-Spect™ Cardiac Scanner System has been subjected to extensive safety testing, performance testing, and validation before release. These tests included EMC and Safety testing according to international standards IEC/EN-60601-1 and IEC/EN 60601-1-2, testing according to the relevant sections of the NEMA NU 1 standard, and software validation testing.

Clinical Performance Data: Sample images from three clinical cases using the D-SPECT device.

Conclusions Drawn from Non-Clinical and Clinical Tests: The performance tests demonstrate that D-SPECT device may be safely and effectively used myocardial perfusion imaging. The software validation and performance validation tests for scintillation cameras (NEMA NU 1), as well as the clinical images provided, demonstrate that the D-SPECT device meets its design and performance specifications and is substantially equivalent to the predicate devices.

Substantial Equivalence: The intended use of the D-Spect™ Cardiac Scanner System is substantially equivalent to the currently distributed predicate Cardiac SPECT systems intended for cardiac nuclear imaging

applications. Furthermore, the basic technological characteristics of the D-Spect™ Cardiac Scanner System are similar to the predicate devices. The differences in the technological characteristics do not raise new questions of safety and effectiveness. Furthermore, the performance data support the safety and effectiveness of the new device. Consequently, the D-Spect™ Cardiac Scanner System is substantially equivalent to the Virgo and Cardiarc predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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OCT 2 0 2006

Re: K062450
Trade/Device Name: D-Spect™ Cardiac Scanner System
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: August 17, 2006
Received: August 22, 2006

Dear Ms. Stein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K062450

Device Name: D-Spect™ Cardiac Scanner System

Indications for Use:

D-SPECT is an emission computed tomography system intended to detect the location and distribution of gamma ray radionuclides in the body and produce cross-sectional images through computer reconstruction of the data. The device includes display equipment, patient and equipment supports, component parts, and accessories.

D-SPECT is primarily intended for cardiac applications. D-SPECT supports radionuclides within the energy range of 40 -170 keV.

Prescription Use __√__ (Per 21 C.F.R. 801 Subpart D) OR Over-The-Counter Use___ (Optional Format Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K062450